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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/684,016	10/10/2000	David K. Kovalic	16517.031	9497

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ARNOLD & PORTER  
IP DOCKETING DEPARTMENT; RM 1126(b)  
555 12TH STREET, N.W.  
WASHINGTON, DC 20004-1206

EXAMINER

ZHOU, SHUBO

ART UNIT	PAPER NUMBER
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1631

15

DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/684,016

Applicant(s)

KOVALIC ET AL.

Examiner

Shubo "Joe" Zhou

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 August 2002 and 10 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-16 is/are rejected.
- 7) ☒ Claim(s) 13 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicant's response, filed 4/10/03, to the Office communication mailed 10/21/02 is acknowledged. Since applicant provided evidence that the previous response filed 8/8/02 did contain a markup version of the amendment to claim 14, the amendment is thus deemed responsive. The non-responsive amendment letter mailed 10/21/02 is hereby rescinded.

Applicant's amendment and request for reconsideration in Paper #12, filed on 8/8/02, is acknowledged and the amendments entered.

Currently, claims 11-16 are pending and under consideration.

Applicant's arguments in response to the previous Office Action of 5/8/02 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous Office action are hereby withdrawn. The following rejections and/or objections are either reiterated from the previous Office action(s) or newly added, and constitute the complete set presently being applied to the instant application.

### ***Claim Rejections-35 USC § 101/§ 112***

**Claims 11-15 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility.**

This rejection is reiterated from previous Office action and maintained for reasons of record.

Applicant cites a series of case law and argues that the invention has a specific and substantial utility because it can be used to identify the presence or absence of a polymorphism in a population of plants. This is not deemed persuasive. Since the function of the gene

comprising the claimed sequence is not known, identifying the presence or absence of a polymorphism in a population is not deemed a real world utility. As set forth in the previous Office action (page 5) since further research has to be done in order to determine the function of the gene comprising the claimed sequence, and also the significance of the presence or absence of polymorphism of the gene in a population, such clear need of further research indicates that the polynucleotides and protein encoded thereby is not disclosed as to a currently available substantial utility.

**Newly added claim 16 is rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility.**

This rejection is newly added and the claim is rejected for the same reasons of record as applied to claims 11-15 in the previous Office action.

**Claims 11-15 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.**

This rejection is reiterated from previous Office action and maintained for reasons of record. Since applicant's arguments for the above rejection under 35 U.S.C. 101 are not deemed persuasive, the arguments in response to this rejection are deemed non-persuasive for the same reasons as set forth above.

**Newly added claim 16 is also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.**

This rejection is newly added and the claims are rejected for the same reasons of record as applied to claims 11-15 in the previous Office action.

***Claim Rejections-35 USC § 112, First Paragraph***

**Claims 11-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.**

This rejection is reiterated from previous Office action and maintained for reasons of record. This is a written description rejection.

Applicant argues that the specification provides a detailed chemical structure for the invention and allows one of skill in the art to recognize that applicants invented what is claimed. This is not deemed persuasive. As set forth in the previous Office action, the specification only provides sequences of the elected SEQ ID No:48411, but not the sequences comprising the sequence of the elected SEQ ID NO or comprising a fragment thereof. As set forth in the previous Office action (pages 6-8), the claimed invention is a genus and there is substantial variability among the species of polynucleotides or nucleic acids encompassed within the scope

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of the claims because the claimed SEQ ID NO is itself only a fragment of any full-length genes or cDNA species, or any vector due to the use of the open language “comprising”. Since the claimed genus encompasses species yet to be discovered, e.g. the full length cDNA and full length genes comprising the elected sequence, etc., the mere disclosure of a species: sequences of the claimed SEQ ID NOs, does not provide an adequate description of the claimed genus.

**Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.**

Claim 14 is amended to recite “a substantially purified nucleic acid having between 90% and 100% sequence identity with base pairs 1 through 123 of SEQ ID NO:48411 and a complete complement thereof” in Paper # 12. However, the claim limitation of “base pairs 1 through 123 of SEQ ID NO:48411” is not described in the instant specification, and is considered as new matter.

The following is a quotation of the **second** paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

Claim 15 recites the limitation " said second nucleic acid molecule " in line 3. There is insufficient antecedent basis for this limitation in the claim.

Clarification and correction is needed.

***Claim Rejections-35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claim 13 is rejected under 35 U.S.C. § 102(b) as being anticipated by Mahairas et al. (GenEmbl Acc. No. AQ451805, 4/21/1999).**

This rejection is reiterated from the previous Office action and maintained for reasons of record.

Applicants argue that since the claim recites “complete complement”, the rejection is improper. This is not found persuasive. The claim did recite simply “complements” twice, but the amended claim recites “complete complement”. The amended claim, however, is still anticipated by Mahairas et al.

The amended claim 13 is interpreted as claiming a nucleic acid comprising a fragment of about 30 to about 50 nucleotides long, but the claim does not indicate this fragment of 30-50 bps is from SEQ ID NO:48411. Thus this fragment can be any nucleic acid fragment of about 30-50 bps long. The claim also requires that this fragment exhibits complete complementary to a second fragment of SEQ ID NO:48411. As set forth in the previous Office action, absent a

definition for the term “fragment” of SEQ ID NO:48411, one or more nucleotides are considered as fragment. Thus, nucleotides 98-118 of SEQ ID NO:48411 is a fragment of SEQ ID NO:48411. The nucleic acid molecule disclosed by Mahairas et al. contains a fragment of around 30 and that fragment is completely complementary to the fragment of nucleotides 98-118 of SEQ ID NO:48411 as shown in the sequence alignment provided to applicants in the previous Office action. Complete complementarity here is interpreted as being that every nucleotide of the fragment of nucleotides 98-118 of SEQ ID NO:48411 is matched by a nucleotide from the fragment of the nucleic acid molecule disclosed by Mahairas et al.

If amendmend would be made to insert “of SEQ ID NO:48411” after “30 to about 50 nucleotide residues”, the rejection would appear to be overcome.

### ***Claim Objections***

Claim 13 is objected to because of the following informalities:

Claim 13 recites “having a nucleic acid sequence having the nucleic acid sequence of”.

Deleting the first part “having a nucleic acid sequence” is suggested.

Appropriate correction is required.

### ***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703)305-3014.

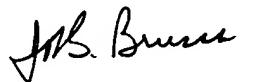
Any inquiry concerning this communication or earlier communications from the examiner should be directed to:  
Shubo "Joe" Zhou, Ph.D., whose telephone number is (703) 605-1158. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst Tina Plunkett whose telephone number is 703)-305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

S. "Joe" Zhou, Ph.D.

Patent Examiner



JOHN S. BRUSCA, PH.D.  
PRIMARY EXAMINER